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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/008,456

11/02/2001

Timothy R. Owens

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5019

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10/17/2007

BLAKELY SOKOLOFF TAYLOR & ZAFMAN
1279 OAKMEAD PARKWAY
SUNNYVALE, CA 94085-4040

EXAMINER

ROY, BAISAKHI

ART UNIT

PAPER NUMBER

3737

MAIL DATE

DELIVERY MODE

10/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/008,456

Applicant(s)

OWENS ET AL.

Examiner

Baisakhi Roy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION***Response to Arguments***

Applicant's arguments filed 6/6/07 have been fully considered but they are not persuasive. With respect to obtaining a pre-procedure image, Badano et al. teach obtaining a pre-insertion image of the markers, which are disposed on a support element received by the insert. The pre-procedure image enables the surgeon to follow a preprogrammed surgical approach on the pre-procedure image. Badano et al. teach obtaining a pre-procedure image of said markers, which are placed on the anatomical surface by the support elements (col. 6 lines 39-43). Badano et al. teach obtaining the geometry information of the plurality of target markers, obtaining coordinate information of the marker elements in the frame of reference of the pre-procedure images (col. 7 lines 25-29). Gillies et al. teach a device used in conjunction with magnetic stereotaxis guidance and device delivery and a method for MR-guided targeted drug delivery into a patient. It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Badano et al. to modify the teaching by Gillies et al. for the purpose of obtaining a pre-procedure image of the marker and enable the operator to accurately implement follow-up procedures and register the coordinates of the stored image of the device over the image of the anatomy (col. 6 lines 21-24, col. 7 lines 11-29).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 4-10, 13-24, 27-35, 38-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gillies et al. in view of Badano et al. (6,167,292).

Gillies et al. teach an apparatus and method of inserting a medical device such as a catheter with a plurality of target markers into an anatomy, scanning a MRI image of the anatomy with said MRI processor having the ability to detect low-level signals, processing the scanned image, determining a location and orientation of the medical device in relation to the anatomy, and displaying a precise image of the device within the anatomy where the device is not depicted as noise for MRI systems (col. 6 lines 27-49, col. 8 lines 16-31, col. 11 lines 5-13, col. 14 lines 41-60, col. 27 lines 7-40).

Gillies et al. teach said medical device to be expandable and composed of polymer material (col. 25 lines 15-25, col. 28 lines 52-55).

Gillies et al. teach superimposing an image of the medical device over the anatomy by replacing a plurality of pixels of an anatomy with a plurality of pixels of the medical device (col. 11 lines 5-13 lines 31-64).

Gillies et al. teach a MRI system comprising a scanner, a processor, a control unit, and a display with the ability to detect low-level signals from a medical device with a plurality of target markers which is inserted into an anatomy, where the device is not depicted as noise for MRI systems, and the location and orientation of said device is determined prior to insertion into an anatomy (col. 6 lines 27-49, col. 8 lines 16-31, col. 11 lines 5-13, col. 14 lines 41-60, col. 27 lines 7-40).

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Gillies et al. however do not explicitly teach pre-scanning the medical device before inserting in an anatomy. In the same field of endeavor Badano et al. disclose a system and method where information for the plurality of target markers is stored in a MR system prior to insertion of the device into the anatomy (col. 6 lines 26-43). Badano et al. further teach the registration of the patient anatomy with the image space where the coordinates of the markers in the frame of reference of the images and in the frame of reference of the robot are compared making it possible to bring patient space into registration with the image space (col. 8 lines 25-67, col. 9 lines 1-15). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Badano et al. to modify the teaching by Gillies et al. for the purpose of obtaining a pre-procedure image of the marker and enable the operator to accurately implement follow-up procedures and register the coordinates of the stored image of the device over the image of the anatomy (col. 6 lines 21-24, col. 7 lines 11-29).

3. Claims 2, 3, 11, 12, 25, 26, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gillies et al. in view of Badano et al. and further in view of Young et al.

Regarding claims 2, 11, 25, and 36, Gillies et al. teach the use of a plurality of target markers as set forth above, but do not explicitly teach said markers to be one of ferromagnetic and paramagnetic material. In the same field of endeavor, Young et al. teach said medical device to be composed of paramagnetic material (col. 6 lines 34-65, col. 12 lines 37-67, col. 13 lines 1-20). It would have therefore been obvious to one of ordinary skill in the art to use the marker material composition teaching by Gillies et al.

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and Badano et al. to modify the teaching by Young et al. for the purpose of using a paramagnetic material to generate images with enhanced visibility of the medical device.

Regarding claims 3, 12, 26, and 37, Gillies et al. do not explicitly teach the magnetic field strength of the MRI system. It is well known in the art that diagnostic MRI system employ magnets with operating field strengths in the range of 0.02 T to 1.5 T. In the same field of endeavor, Young et al. teach the use of a MRI system operating at 1.5 Tesla (col. 14 lines 10-15). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Young et al. to modify the teaching by Gillies et al. for the purpose of applying an appropriate magnetic field strength.

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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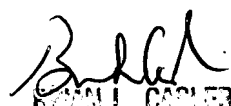
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Baisakhi Roy whose telephone number is 571-272-7139. The examiner can normally be reached on M-F (7:30 a.m. - 4p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BR

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BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNICAL CENTER 3100